

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

U.S. Patent No. 5,540,938

Application No. 08/328,165

Issued: July 30, 1996

Filing Date: October 24, 1994

Patentee: Joseph G. Masterson et al.

Attorney Docket No. 12952-033-999

For: FORMULATIONS AND THEIR USE IN THE  
TREATMENT OF NEUROLOGICAL DISEASES

**REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.323**

**ATTN: Certificate of Correction Branch**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to Manual of Patent Examining Procedure §§ 1481 and 1481.03(II)(A) (8th ed., rev. 8, 2010) [hereinafter MPEP], Patentee respectfully requests issuance of a Certificate of Correction in connection with the above-identified patent. Enclosed please find the errors, as they appear in the patent, in the attached form PTO/SB/44, as follows:

On the face page of the patent, in the Related U.S. Application Data section (item [62]), cancel the text reading “Division of Ser. No. 786,400, Nov. 1, 1991, abandoned, and a division of Ser. No. 73,651, Jun. 7, 1993, Pat. No. 5,370,879” and insert the following text:

--Division of Ser. No. 73,651, Jun. 7, 1993, Pat. No. 5,370,879, which is a continuation of Ser. No. 786,400, Nov. 1, 1991, abandoned.--

Column 1, line 5, cancel the text beginning with “This is a divisional” to and ending “U.S. Pat. No. 5,370,879.” in column 1, line 7, and insert the following text:

--This is a divisional of Ser. No. 08/073,651, filed Jun. 7, 1993, now U.S. Pat. No. 5,370,879, which is a continuation of Ser. No. 07/786,400, filed Nov. 1, 1991, now abandoned.--

Patentee asserts that the proposed correction meets the statutory requirements for certificate of correction, in that it is of a typographical or clerical nature and does not constitute new matter or require reexamination. *See MPEP § 1481*. Furthermore, the proposed correction meets the requirements set forth in MPEP § 1481.03(II)(A) for using a certificate of correction to correct a 35 U.S.C. § 120 priority claim in applications filed before November 29, 2000.<sup>1</sup> Specifically, MPEP § 1481.03(II)(A) states that a certificate of correction can be used to correct an incorrect reference to a prior copending application pursuant to old rule 37 C.F.R. §§ 1.78(a)(2) and (a)(4) if the following conditions are met:

*(A) for 35 U.S.C. 120 priority, all requirements set forth in 37 CFR 1.78(a)(1) must have been met in the application which became the patent to be corrected; (B) for 35 U.S.C. 119(e) priority, all requirements set forth in 37 CFR 1.78(a)(3) must have been met in the application which became the patent to be corrected; and (C) it must be clear from the record of the patent and the parent application(s) that priority is appropriate.*

Patentee asserts that all of the above conditions are met.

Regarding condition (A), all requirements set forth in old rule 37 C.F.R. § 1.78(a)(1) were met in the application which became the subject patent. Specifically, applications nos. 08/073,651 and 07/786,400 and the instant patent to be corrected all name Joseph G. Masterson and Michael Myers as inventors, thus satisfying the inventorship overlap requirement of old rule 37 C.F.R. § 1.78(a)(1). Furthermore, the priority applications disclose the named inventors' invention in at least one claim of the application issuing as the instant patent in a manner provided by the first paragraph of 35 U.S.C. § 112 (the respective specifications are substantially identical). Finally, each priority application as filed was complete under 37 C.F.R. § 1.51(b). *See Application Transmittal Form (37 C.F.R. § 1.62) in app. no. 08/073,651 dated June 7, 1993 [attached hereto as Exhibit A], at page 1; New Application Transmittal in app. no. 07/786,400 dated November 1, 1991 [attached hereto as Exhibit B], at page 1.*

The requirements of condition (B) are not relevant, since priority is not claimed under 35 U.S.C. § 119(e).

Regarding condition (C), Patentee submits that it is clear from the record of the patent and the priority applications that priority is appropriate. In the first instance, the transmittal paper for the application which became the subject patent specifically states that the application

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<sup>1</sup> MPEP § 1481.03(II)(A) relates to correction as to 35 U.S.C. §§ 120 and 119(e) benefits in applications filed before November 29, 2000, and notes that the version of 37 C.F.R. § 1.78 which was in effect as of November 29, 2000 applies. This version of § 1.78 is referred to herein as "old rule 37 C.F.R. § 1.78."

is a divisional of parent application no. 08/073,651. *See* Transmittal of Filing Under 37 CFR 1.60(b) dated October 21, 1994 [attached hereto as Exhibit C], at page 1. Indeed, the § 120 priority claim at page 4 of Exhibit C states this relationship correctly. Furthermore, parent application no. 08/073,651 itself clearly in turn is a continuation of grandparent application no. 07/786,400, as evidenced by Exhibit A, at page 1 (the box labeled “continuation” is checked).<sup>2</sup> *See also* U.S. Patent No. 5,370,879, issued from application no. 08/073,651, at its face page [attached hereto as Exhibit D] (indicating that the patent is a “Continuation of Ser. No. 786,400, Nov. 1, 1991”). Thus, the record makes clear that the application which became the subject patent is actually a divisional of application no. 08/073,651, which in turn is a continuation of application no. 07/786,400.

This error in the priority claim (set forth at page 4 of Exhibit C), specifically in incorrectly identifying the prior application, occurred in good faith.

Patentee provides herewith the fee for providing a correction of applicant’s mistake under 37 C.F.R. § 1.20(a) estimated to be \$100, to be charged to Jones Day Deposit Account No. **50-3013**.

Accordingly, Patentee respectfully requests issuance of the attached Certificate of Correction. Should any additional fees be required, the Commissioner is authorized to charge such fees to Jones Day Deposit Account No. **50-3013**.

Respectfully submitted,

Date: April 11, 2012

Adriane M. Antler 32,605  
Adriane M. Antler Reg. No.  
**JONES DAY**  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939

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<sup>2</sup> Old rule 37 C.F.R. § 1.62 provided for a “file wrapper continuation,” which was essentially a continuation, divisional, or continuation-in-part of an application that uses the specification, drawings, oath or declaration, and file wrapper and contents, of its parent application to constitute the new application, and the rule specifies that the parent application is abandoned upon filing the new application.

# EXHIBIT A



260.00 101A Fw C  
10/073651 #12/C  
JPD  
7/20/93

### APPLICATION TRANSMITTAL FORM (37 C.F.R. § 1.62)

ATTORNEY DOCKET NO.: 9318MC.US

ANTICIPATED CLASSIFICATION OF THIS APPLICATION:

PRIOR APPLICATION:

CLASS: 424

SUBCLASS:

EXAMINER:

C. Azpuru

ART UNIT:

1502

To the Commissioner of Patents and Trademarks

Box FWC

Washington, D.C. 20231

This is a request for filing a [ ] continuation-in-part, [X] continuation, [ ] divisional application under 37 CFR § 1.62, of prior application Serial No. 07/786,400, filed on November 1, 1991, entitled "Formulations and their use in the treatment of neurological diseases" by the following named inventor(s).

FULL NAME OF INVENTOR	FAMILY NAME: Masterson	FIRST GIVEN NAME: Joseph	SECOND GIVEN NAME: Gerard
RESIDENCE & CITIZENSHIP	CITY: London	STATE OR FOREIGN COUNTRY: GBX U.K.	COUNTRY OF CITIZENSHIP: Ireland
POST OFFICE ADDRESS	ADDRESS: 33 Rosaville Road	CITY: London SW6 7BN	STATE & ZIP CODE/COUNTRY: U.K.

FULL NAME OF INVENTOR	FAMILY NAME: Myers	FIRST GIVEN NAME: Michael	SECOND GIVEN NAME:
RESIDENCE & CITIZENSHIP	CITY: Athlone	STATE OR FOREIGN COUNTRY: IEX Ireland	COUNTRY OF CITIZENSHIP: Ireland
POST OFFICE ADDRESS	ADDRESS: 71, Retreat Park	CITY: Athlone	STATE & ZIP CODE/COUNTRY: Ireland

The above-identified prior application in which no payment in the issue fee, abandonment of, or termination of proceedings has occurred, is hereby expressly abandoned as of the filing date of this new application. Please use all the contents of the prior application file wrapper, including the drawings, as the basic papers for the new application.

(Note: 37 C.F.R. § 1.60 may be used for applications where the prior application is not to be abandoned.)

- [ ] Enter the amendment previously filed on \_\_\_\_\_ under 37 C.F.R. § 1.116 but unentered, in the prior application.
- [X] A preliminary amendment will be filed under separate cover.

The filing fee is calculated on the basis of the claims existing in the prior application as amended at 1 and 2 above.

(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
TOTAL CLAIMS	45 - 20 =	0	X \$22.00	\$550.00
INDEPENDENT CLAIMS	2 - 3 =	0	X \$74.00	\$-0-
MULTIPLE DEPENDENT CLAIM(S) (IF APPLICABLE) =	0		+ \$230.00	\$-0-
BASIC FEE =				\$710.00
TOTAL OF ABOVE CALCULATIONS =				\$1,260.00
REDUCTION BY 1/2 FOR FILING BY SMALL ENTITY (NOTE 37 CFR §§ 1.9, 1.27, 1.28) IF APPLICABLE, AFFIDAVIT MUST BE FILED ALSO.				\$
TOTAL FEE =				\$1,260.00

3.  The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 05-0670. A duplicate of this sheet is attached.

4.  A check in the amount of \$1,260.00 is enclosed.

5.  A new oath or declaration is included since this application is a continuation-in-part which discloses and claims additional matter.

6.  Amend the specification by inserting before the first line the sentence:

This application is a  continuation-in-part,  continuation,  division, of application Serial No. 07/786,400, filed November 1, 1991, *now abandoned*

7.  A verified statement claiming small entity status under 37 C.F.R. §1.9 and §1.27

is enclosed

was filed in the prior application and such status is still proper and desired  
(37 C.F.R. § 1.28(a))

8.  Priority of application Serial No. 3952/90 filed on February 11, 1990 in Ireland is claimed under 35 U.S.C. § 119.

9.  The prior application is assigned of record to: **Elan Corporation, plc**

10.  The Power of Attorney in the prior application is to:

Marla J. Church, Esq.  
Reg. No. 29,908

- a.  The power appears in the original papers in the prior application.
- b.  An Associate Power does not appear in the original papers.
- c.  A new power has been executed and is attached.

11.  A petition, fee and response has been filed to extend the term in the pending **prior** application until June 7, 1993 (three-month extension of time).

a copy of the petition for extension of time in the **prior** application is attached.

12.  Enclosed:  Three month extension of time to **June 7, 1993** for  
Serial No. 07/786,400, the prior application.  
 Check in the amount of **\$840.00** for the three month EOT.

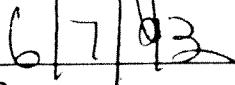
Address all future communications to:

ATTORNEY: Marla J. Church, Esq.  
ELAN PHARMACEUTICAL RESEARCH CORPORATION  
1300 Gould Drive  
Gainesville, GA 30504  
(404) 534-8239

It is understood that secrecy under 35 U.S.C. § 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 C.F.R. § 162 application, be it either this application or a prior application in the same file wrapper, the Patent and Trademark Office may provide similar information or access to all the other applications in the same file wrapper.



Signature



Date

inventor(s)

assignee of complete interest

attorney or agent of record

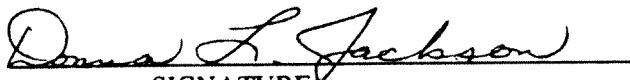
filed under §1.34(a)

**CERTIFICATE OF EXPRESS MAILING**  
**EXPRESS MAIL NO. IB763595877**

The undersigned individual on behalf of applicant, Elan Corporation, plc, hereby certifies that the foregoing continuation application under 37 CFR § 1.62, of prior application Serial No. 07/786,400 filed on 11/1/91, and a check in the amount of \$1,260.00, which represents the filing fee, is being deposited with the United States Postal Service as Express Mail No. IB763595877 in an envelope addressed to:

Honorable Commissioner of  
Patents and Trademarks  
Box FWC  
Washington, D.C. 20231

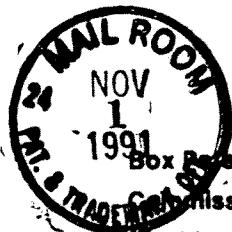
on this 7th day of June, 1993.

  
\_\_\_\_\_  
SIGNATURE

6-7-93  
\_\_\_\_\_  
DATE

IA1806162FWC

# EXHIBIT B



07 786400  
PATENT

Docket No. 91.1806.US

Box Patent Application  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

### NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of  
Inventor(s): Joseph Gerard Masterson and Michael Myers

**WARNING:** Patent must be applied for in the name(s) of all of the actual inventor(s). 37 CFR 1.41(a) and 1.53(d).

For (title): FORMULATIONS AND THEIR USE IN THE TREATMENT OF NEUROLOGICAL DISEASES

#### 1. Type of Application

This new application is for a(n) (check one applicable item below):

- Original
- Design
- Plant

**WARNING:** Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4) unless the International Application is being filed as a divisional, continuation or continuation-in-part application.

**NOTE:** If one of the following 3 items apply then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED.

- Divisional
- Continuation
- Continuation-in-part (CIP)

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#### CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date November 1, 1991 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number FB282314263 addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Donna L. Jackson

(Type or print name of person mailing paper)

Donna L. Jackson

(Signature of person mailing paper)

**NOTE:** Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

**2. Benefit of Prior U.S. Application(s) (35 USC 120)**

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

**3. Papers Enclosed Which Are Required For Filing Date Under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design) Application**

39 Pages of specification

12 Pages of claims

1 Pages of Abstract

1 Sheets of drawing

formal

informal

**WARNING:** DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE: "Identifying indicia such as the serial number, group and unit, title of the invention, attorney's docket number, inventor's name, number of sheets, etc., not to exceed 2½ inches (7.0 cm.) in width may be placed in a centered location between the side edges within three fourths inch (19.1 mm.) of the top edge. Either this marking technique on the front of the drawing or the placement, although not preferred, of this information and the title of the invention on the back of the drawings is acceptable." Proposed 37 CFR 1.84(1). Notice of March 9, 1988 (1090 O.G. 57-62).

**4. Additional papers enclosed**

Preliminary Amendment

Information Disclosure Statement

Form PTO-1449

Citations

Declaration of Biological Deposit

Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.

Authorization of Attorney(s) to Accept and Follow Instructions from Representative

Special Comments

Other

**5. Declaration or oath**

Enclosed  
executed by (check all applicable boxes)

inventor(s).

legal representative of inventor(s). 37 CFR 1.42 or 1.43

joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

this is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. See item 13 below for fee.

Not Enclosed.

**WARNING:** Where the filing is a completion in the U.S. of an International Application but where a declaration is not available or where the completion of the U.S. application contains subject matter in addition to the International Application the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.

Application is made by a person authorized under 37 CFR 1.41(c) on behalf of all the above named inventor(s). The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently.

**NOTE:** It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).

Showing that the filing is authorized. (Not required unless called into question. 37 CFR 1.41(d).

**6. Inventorship Statement**

**WARNING:** If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.

The inventorship for all the claims in this application are:

The same  
or

Are not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

is submitted.

will be submitted.

**7. Language**

**NOTE:** An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of \$30.00 required by 37 CFR 1.17(k) is required to be filed with the application or within such time as may be set by the Office. 37 CFR 1.52(d).

**NOTE:** A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

English

non-English

the attached translation is a verified translation. 37 CFR 1.52(d).

8. Assignment

An assignment of the invention to Elan Corporation, plc

is attached.

will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment." Notice of May 4, 1990 (1114 D.G. 77-78).

9. Certified Copy

Certified copy(ies) of application(s)

Ireland (country)	3952/90 (appln. no.)	November 2, 1990 (filed)
(country)	(appln. no.)	(filed)
(country)	(appln. no.)	(filed)

from which priority is claimed

is(are) attached. A separate "ASSIGNMENT COVER LETTER ACCOMPANYING NEW PATENT APPLICATION" is also attached.

will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 CFR 1.16)

A.  Regular application

CLAIMS AS FILED			
Number filed	Number Extra	Rate	Basic Fee \$630.00
Total Claims 37 CFR 1.16(c)45 - 20 = 25	X	\$ 20.00	\$ 500.00
Independent Claims (37 CFR 1.16(b))2 - 3 = 0	X	\$ 60.00	-
Multiple dependent claim(s), if any (37 CFR 1.16(d)) -0-		\$200.00	\$ -

Amendment cancelling extra claims enclosed.

Amendment deleting multiple-dependencies enclosed.

Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation \$ 1,130.00

(Application Transmittal [4-1]—page 4 of 7)

B.  **Design application**  
(\$250.00—37 CFR 1.16(f))

Filing Fee Calculation \$ \_\_\_\_\_

C.  **Plant application**  
(\$420.00—37 CFR 1.16(g))

Filing fee calculation \$ \_\_\_\_\_

**11. Small Entity Statement(s)**

Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached.

Filing Fee Calculation (50% of A, B or C above) \$ \_\_\_\_\_

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. 37 CFR 1.28(a).

**12. Request for International-Type Search (37 CFR 1.104(d)) (complete, if applicable)**

Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

**13. Fee Payment Being Made At This Time**

Not Enclosed

No filing fee is to be paid at this time. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

Enclosed

basic filing fee \$ 1,130.00

recording assignment (\$8.00; 37 CFR 1.21(h)) \$ \_\_\_\_\_

petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. (\$120.00; 37 CFR 1.47 and 1.17(h)) \$ \_\_\_\_\_

for processing an application with a specification in a non-English language. (\$30.00; 37 CFR 1.52(d) and 1.17(k)) \$ \_\_\_\_\_

processing and retention fee (\$120.00; 37 CFR 1.53(d) and 1.21(l)) \$ \_\_\_\_\_

fee for international-type search report (\$30.00; 37 CFR 1.21(e)). \$ \_\_\_\_\_

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid or the processing and retention fee of § 1.21(l) must be paid within 1 year from notification under § 53(d).

Total fees enclosed \$ 1,130.00

**14. Method of Payment of Fees**

Check in the amount of \$ 1,130.00

Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ A  
duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

**15. Authorization to Charge Additional Fees**

**WARNING:** If no fees are to be paid on filing the following items should not be completed.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.

The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. 05-0670

37 CFR 1.16(a), (f) or (g) (filing fees)

37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

37 CFR 1.17 (application processing fees)

**WARNING:** While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that "Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee". From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

**16. Instructions As To Overpayment**

credit Account No. 05-0670

refund

Reg. No. 29,908 301

Tel. No. (404) 534-8239

  
SIGNATURE OF ATTORNEY

601 MARLA J. CHURCH

Type or print name of attorney

602 Elan Pharmaceutical Research Corporation

700 Address 1300 Gould Drive

702 Gainesville, Georgia 30504

**Incorporation by reference of added pages**

*Check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED*

Plus Added Pages For New Application Transmittal Where Benefit Of Prior U.S. Application(s) Claimed

Number of pages added \_\_\_\_\_

Plus Added Pages For Papers Referred To In Item 4 Above

Number of pages added \_\_\_\_\_

Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added \_\_\_\_\_

**Statement Where No Further Pages Added**

*(If no further pages form a part of this Transmittal then end this Transmittal with this page and check the following item)*

This transmittal ends with this page.

# EXHIBIT C

730 QD PLA  
328165  
PATENT

Attorney's Docket No. 93.1806C.US



UNITED STATES PATENT AND TRADEMARK OFFICE

Anticipated Classification of this application:

Class 424 Subclass       

Prior application:

Examiner: C. Azpuru

Art Unit: 1502

Box Patent Application  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

TRANSMITTAL OF FILING UNDER 37 CFR 1.60(b)

**WARNING:** A c-i-p (continuation-in-part) cannot be filed under 37 CFR 1.60.

**WARNING:** Filing under 37 CFR 1.60 is permitted only if filed by the same or less than all the inventors named in the prior application. 37 CFR 1.60(b)(3).

**WARNING:** The filing of an application at the United States stage of an International Application requires an oath or declaration. 37 CFR 1.61(a)(4).

**WARNING:** The claims of this new application may be finally rejected in the first Office action where all claims of the new application are drawn to the same invention claimed in the earlier application and would have been properly finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. MPEP § 708.07(b).

This is a request for filing a

Continuation  
 Divisional

application under 37 CFR 1.60, of pending prior application

Serial No. 08/ 073,651 filed on June 7, 1993  
(Date)

of Joseph Gerard Masterson and Michael Myers  
(Inventor(s))

for "Formulations and their use in the treatment of  
(Title of invention)  
neurological diseases"

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this 37 CFR 1.60 request and the documents referred to as attached therein are being deposited with the United States Postal Service on this date October 21, 1994 in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10, Mailing Label Number EF988211032US addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Donna L. Jackson

(type or print name of person mailing paper)

Donna L. Jackson  
(Signature of person mailing paper)

NOTE: Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. (37 CFR 1.10(b)).

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 CFR 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

(37 CFR 1.60(b) [4-3]—page 1 of 8)

NOTE: 37 CFR 1.60 permits the omission of a declaration only if the prior application was complete as set forth in 37 CFR 1.51(a), namely, the prior application comprised at least (1) a specification, including a claim or claims; (2) a declaration; (3) drawings when necessary; and (4) the prescribed filing fee. Accordingly, as presently worded, 37 CFR 1.60 does not permit this procedure to be used where the prior application is pending but only the processing and retention fee required by 37 CFR 1.21(f) is paid or where the declaration was not filed.

### 1. Copy of Prior Application as Filed Which is Attached

NOTE: Under 37 CFR 1.60, practice signing and execution of the application by the applicant may be omitted provided the copy is supplied by and accompanied by a statement by the applicant or his or her attorney or agent that the application papers comprise a true copy of the prior application as filed and that no amendments referred to in the declaration filed to complete the prior application introduced new matter therein.

NOTE: This statement need not be verified if made by an attorney registered to practice before the PTO. (37 CFR 1.60(b)).

I hereby verify that the attached papers are a true copy of what is shown in my records to be the above identified prior application, including the oath or declaration originally filed (37 CFR 1.60).

The copy of the papers of prior application as filed which are attached are as follows:

39 page(s) of specification  
 12 page(s) of claims  
 1 page(s) of abstract  
 1 sheet(s) of drawing

(also complete part 6 below if drawings are to be transferred)

4 pages of declaration and power of attorney

(If the copy of the declaration being filed does not show applicant's signature, because the attorney's records do not contain a copy of the signed declaration actually filed for the application, indicate thereon that it was signed and complete the following:)

in accordance with the indication required by 37 CFR 60(b), my records reflect that the original signed declaration showing applicant's signature was filed on \_\_\_\_\_

the amendment referred to in the declaration filed to complete the prior application and I hereby state, in accordance with the requirements of 37 CFR 1.60(b), that this amendment did not introduce new matter therein.

### 2. Amendments

**WARNING:** "The claim of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application." MPEP § 706.07(b).

Cancel in this application original claims 1-37 of the prior application before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)

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A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively beginning with the number next following the highest numbered original claim in the prior application.)

NOTE: Only amendments reducing the number of claims or adding a reference to the prior application (Rule 1.78(a)) will be entered before calculating the filing fee and granting the filing date. 37 CFR 1.60(b).

NOTE: "When filing under Rule 1.60 retain at least one original claim from the patent application to assure a complete application." Notice of March 3, 1986 (1064 O.G. 37-38).

### 3. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

NOTE: Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary).

(check the next item, if applicable)

There is provided herewith a Petition To Suspend Prosecution For The Time Necessary to File An Amendment (New Application Filed Concurrently).

### 4. Information Disclosure Statement

(check this item, if applicable)

An information disclosure statement is submitted herewith.

### 5. Fee Calculation (37 CFR 1.16)

CLAIMS AS FILED				
Number filed	Number Extra	Rate	Basic Fee	
			37 CFR 1.16(a)	
			\$730.00	730.00
<b>Total</b> Claims (37 CFR 1.16(c))	8 - 20 =	×	\$ 22.00	-0-
Independent Claims (37 CFR 1.16(b))	1 - 3 =	×	\$ 76.00	-0-
Multiple dependent claim(s), if any (37 CFR 1.16(d))	0	+	\$230.00	-0-

Fee for extra claims is not being paid at this time. (37 CFR 1.16(d))

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation \$ 730.00

### 6. Small Entity Status

A verified statement that this filing is by a small entity:

- is attached
- has been filed in the parent application and such status is still proper and desired (37 CFR 1.28(a))

Filing Fee Calculation (50% of above) \$

NOTE: Any excess of the full fee paid will be refunded if a verified statement is filed within 2 months of the date of timely payment of a full fee then the excess fee paid will be refunded on request. 37 CFR 1.28(a).

NOTE: 37 CFR 1.28(a), last sentence states: "Applications filed under § 1.60 or § 1.62 of this part must include a reference to a verified statement in a parent application if status as a small entity is still proper and desired."

7. Drawings

Drawings are enclosed  
 formal  
 informal

**WARNING:** DO NOT submit original drawings. A high quality copy of drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards of § 1.84. If corrections to the drawings are necessary, they should be made to the original drawings and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired.  
Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1090 O.G. 57-62).

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c)).

8. Priority—35 U.S.C. 119

Priority of application Serial No. 0xx/ 3952/90 filed on November 2, 1990 in Ireland is claimed under 35 U.S.C. 119. (country)  
 The certified copy has been filed in prior U.S. application Serial No. 07/ 786,400 on 11/1/91  
 The certified copy will follow.

9. Relate Back—35 U.S.C. 120

Amend the specification by inserting before the first line the sentence:

"This is a

continuation  
 divisional

of copending application(s)

Serial number 07/ 786,400 filed on 11/1/91 <sup>now abandoned</sup>, and Serial No. 08/073,651 filed 6/7/93 and which designated the U.S.  
 International Application \_\_\_\_\_ filed on \_\_\_\_\_ and

<sup>now U.S. Pat No.</sup>  
<sup>5,370,879</sup>

NOTE: The proper reference to a prior filed PCT application which entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application which designated the U.S.

10. Inventorship Statement

NOTE: If the continuation or divisional application is filed by less than all the inventors named in the prior application a statement must accompany the application when filed requesting deletion of the names of the person or persons who are not inventors of the invention being claimed in the continuation or divisional application. 37 CFR 1.60(b) [emphasis added].

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(complete appropriate items (a) and (b))

(a) With respect to the prior copending U.S. application from which this application claims benefit under 35 USC 120 the inventor(s) in this application is (are):

(complete applicable item below)

the same  
 less than those named in the prior application and it is requested that the following inventor(s) identified above for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

(b) The inventorship for all the claims in this application are

the same  
 not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made, is submitted.

11. Assignment

The prior application is assigned of record to

Elan Corporation, plc

An assignment of the invention to \_\_\_\_\_

is attached. A separate  "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or  FORM PTO 1595 is also attached.

NOTE: "If an assignment is submitted with a new application, send two separate letters - one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

NOTE: When an assignee files a . . . divisional application (under . . . 1.60 . . .) reference may be made to a statement filed under 37 CFR 3.73(b) in the parent application, or a copy of that statement may be filed. Notice of April 30, 1993, 1150 O.G. 62-64.

12. Fee Payment Being Made At This Time

Not Enclosed

No filing fee is submitted. (This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently).

Enclosed

basic filing fee \$ 730.00

recording assignment  
(\$40.00; 37 CFR

1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW PATENT APPLICATION".)

processing and retention fee  
(\$130.00; 37 CFR 1.53(d)  
and 1.21(l)) \$ \_\_\_\_\_

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application which is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78 indicate that in order to obtain the benefit of a prior U.S. application, either the (37 CFR 1.60(b) (4-3)—page 5 of 8)

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Atty. Docket No. 1806C.US

basic filing fee must be paid or else the processing and retention fee of § 1.21(f) must be paid within 1 year from notification under § 53(d).

Total fees enclosed

\$ 730.00

13. Method of Payment of Fees

Enclosed is a check in the amount of \$ 730.00

Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_  
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that is clear for which purpose the fees are paid. 37 CFR 1.22(b).

14. Authorization To Charge Additional Fees

**WARNING:** If no fees are being paid on filing do not complete this item.

**WARNING:** Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claim charges are authorized.

The Commissioner is hereby authorized to charge the following additional fees which may be required by this paper and during the entire pendency of the application to Account No. 05-0670

37 CFR 1.16 (a), (f) or (g) (filing fees)

37 CFR 1.16 (b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid for those claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)) it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

37 CFR 1.17 (application processing fees)

**WARNING:** While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a) this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a request or petition for extension is filed." [emphasis added]. Notice of November 5, 1985 (1060 O.G. 27).

37 CFR 1.18 (issue fee at or before mailing Notice of Allowance, pursuant to 37 CFR 1.311(b)).

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b)).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

15. Power of Attorney

The power of attorney in the prior application is to  
Marla J. Church, Esq.

29,908

(Attorney)

(Reg. No.)

- a.  The power appears in the original papers in the prior application.
- b.  Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
- c.  A new power has been executed and is attached.
- d.  Address all future communications to Marla J. Church, Esq., Elan Pharmaceutical Research Corp., 1300 Gould Dr., Gainesville, GA 30504. (37 CFR 1.60(b) [4-3]—page 6 of 8)

(item d may only be completed by applicant, or attorney or agent of record)

16. Maintenance of Copendency of Prior Application

(This item must be completed and the papers filed in the prior application if the period set in the prior application has run.)

~~A petition, x, and response has been filed to extend the term in the pending prior application until issuance~~

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the Continuation Application. Notice of November 5, 1985 (1060 O.G. 27).

A copy of the petition for extension of time in the prior application is attached.

17. Conditional Petition for Extension of Time in Prior Application

(complete this item and file conditional petition in the prior application if previous item not applicable)

A conditional petition for extension of time is being filed in the pending parent application.

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the paper constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

A copy of the conditional petition for extension of time in the prior application is attached.

18. Abandonment of Prior Application (if applicable)

**WARNING:** (Do not complete this item if the application being filed is a divisional of the prior application which is not being abandoned)

NOTE: "A registered attorney or agent acting under the provisions of § 1.34(a), or of record, may also expressly abandon a prior application as of the filing date granted to a continuing application when filing such a continuing application." 37 CFR 1.138.

Please abandon the prior application at a time while the prior application is pending or when the petition for extension of time or to revive in that application is granted and when this application is granted a filing date so as to make this application copending with said prior application.

19. Notification in Parent Application of the Filing of This Continuation Application

A notification of the filing of this continuation is being filed in the parent application from which this application claims priority under 35 USC § 120.

20. Statement by Assignee (if applicable)

In accordance with 37 CFR 3.73, I have reviewed the evidentiary documents establishing my/our ownership of the application identified herein, and certify that to the best of my/our knowledge and belief, title is with me/us who seek to take action.

Assignment submitted herewith for recordal

I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the

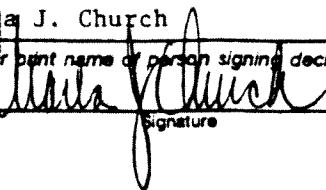
EXPRESS MAIL NO. F988211032US

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like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Marla J. Church

(type or print name of person signing declaration)

  
Signature

October 21, 1994

Date

ELAN PHARMACEUTICAL RESEARCH CORP.

P.O. Address of Signatory

1300 Gould Drive

Gainesville, GA 30504

- Inventor
- Assignee of complete interest
- Person authorized to sign on behalf of assignee
- Attorney or agent of record
- Filed under Rule 34(a)

(1) Tel. No. (404) 534-8239  
Reg. No. 29,908  
(if applicable)

(complete the following if applicable)

Elan Corporation, plc

(Type name of assignee)

Monksland, Athlone,  
Co. Westmeath, Ireland

(Address of assignee)

Corporate Patent Counsel

(Title of person authorized to sign on behalf of assignee)

Assignment recorded in PTO on  
12/17/91

Reel 5960

Frame 0060

The statement under 37 CFR 3.73(b)

- has been filed in the parent application.
- a copy of the statement previously filed in the parent application is attached.

# EXHIBIT D



US005370879A

# United States Patent [19]

Masterson et al.

[11] Patent Number: 5,370,879

[45] Date of Patent: Dec. 6, 1994

[54] **FORMULATIONS AND THEIR USE IN THE TREATMENT OF NEUROLOGICAL DISEASES**

[75] Inventors: Joseph G. Masterson, London, United Kingdom; Michael Myers, Athlone, Ireland

[73] Assignee: Elan Corporation, plc, Athlone, Ireland

[21] Appl. No.: 73,651

[22] Filed: Jun. 7, 1993

0156077 10/1985 European Pat. Off. .... A61K 9/54  
0325843 8/1989 European Pat. Off. .... A61K 9/54

## OTHER PUBLICATIONS

"4-Aminopyridine Tablets; a Method for the Preparation [and] in vitro and in vivo Studies", Uges et al., Pharm. Acta Helv., 57(4) pp. 122-128, 1982, Abstract.  
"4-Aminopyridine in the Treatment of Alzheimer's Disease", Davidson et al., Biol. Psychiatry 23(5), 1988, pp. 485-490.

"4-Aminopyridine Improves Clinical Signs in Multiple Sclerosis", Stefoski et al., Ann. Neurol. 21(1), 1987, pp. 71-77.

Barker, S. & Branford, D.; Pharm. Journal, Jan. 26, 1991, pp. 116-118.

Bever, C. T. Jr; Leslie, J.; Camenga, D. L.; Panitch, H.S.; and Johnson, K. P., Ann. Neurol. 27(4), pp. 421-427 (Apr. 1990).

Wesseling et al., N. Eng. J. of Med. 310 (15), pp. 988-989 (Apr. 1984).

Primary Examiner—Thurman K. Page

Assistant Examiner—Carlos Azpuru

Attorney, Agent, or Firm—Marla J. Church

[57] **ABSTRACT**

Pharmaceutical formulations comprise a mono- or di-aminopyridine active agent for administration on a once- or twice-daily basis for use in the treatment of neurological diseases, in particular multiple sclerosis and Alzheimer's disease. The formulations, which are suitable for oral or percutaneous administration of the active agent, include the active agent in a carrier effective to permit release of the mono- or di-aminopyridine at a rate allowing controlled absorption thereof over, on the average, not less than a 12 hour period and at a rate sufficient to achieve therapeutically effective blood levels over a period of 12-24 hours following administration.

## Related U.S. Application Data

[63] Continuation of Ser. No. 786,400, Nov. 1, 1991, abandoned.

## Foreign Application Priority Data

Feb. 11, 1990 [IE] Ireland ..... 3952/90

[51] Int. Cl. 5 A61K 9/16; A61K 9/50;  
A61K 9/62; A61K 9/70

[52] U.S. Cl. 424/490; 424/445;  
424/449; 424/451; 424/452; 424/458; 424/460;  
424/461; 424/464; 424/465; 424/474; 424/475;  
424/480; 424/484; 424/489; 424/494; 424/495;  
424/497; 424/498; 424/499

[58] Field of Search 424/445, 449, 451, 452,  
424/458, 460, 461, 464, 465, 474, 475, 499, 480,  
484, 489, 490, 494, 495, 497, 498

[56] **References Cited**

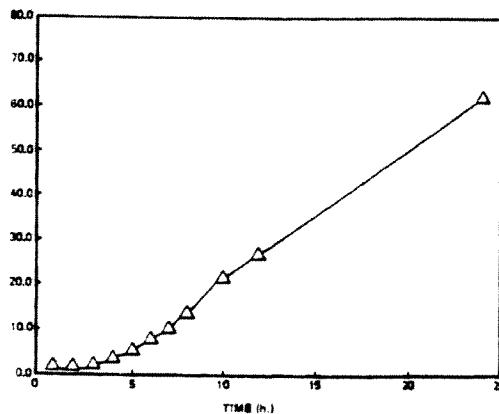
## U.S. PATENT DOCUMENTS

4,386,095 5/1983 Gibson et al. ..... 514/352  
4,562,196 12/1985 Horn et al. ..... 514/332  
4,721,619 1/1988 Panos et al. ..... 424/459  
4,894,240 1/1990 Geoghegan et al. ..... 424/497  
4,946,833 8/1990 Bannon et al. ..... 514/343

## FOREIGN PATENT DOCUMENTS

0117027 1/1984 European Pat. Off. .... A61M 37/00  
0113562 7/1984 European Pat. Off. .... A61M 37/00

27 Claims, 1 Drawing Sheet



4-AP % RELEASE